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10/611,838	06/30/2003	Alan Schaefer	021574-000220US	5147

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EXAMINER

RAMIREZ, JOHN FERNANDO

ART UNIT	PAPER NUMBER
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3737

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09/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/611,838	Applicant(s) SCHAER, ALAN	
	Examiner John F. Ramirez	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/02/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

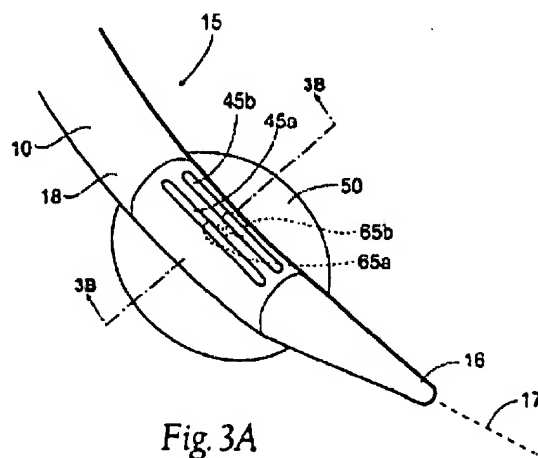
Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

After a review of applicant's remarks, the examiner of record acknowledges the amendments to the claims on page 2-9. Accordingly, original claims 60-62 have been cancelled.

Applicant's arguments filed November 11, 2006 have been fully considered but they are not persuasive. Applicant alleges on pages 11-12 of the remarks, that the Shadduck patent does not teach a "cylindrical vibrational transducer to be positioned with an inflated balloon in the body lumen". However, the examiner of record disagrees with applicant's comments. Figures 3A, 4, 11A, 7B, of the Shadduck patent shows a cylindrical vibrational transducer to be positioned with an inflated balloon in the body lumen. Additionally, in column 8, lines 17-31; in column 9, lines 8-21; in column 12, lines 29-46; and in column 15, lines 41-46, the specifications of the Shadduck patent specifically states:



Referring to FIG. 3A, the working end 15 carries at least one electrode in an electrode array 44, and preferably carries a plurality of Rf electrodes 45a-45n that are positioned in the surface 46 of working end 15. FIGS. 1 and 3A show two exemplary electrodes 45a-45b arranged longitudinally in extension member 10 in a spaced relationship in surface 46. The electrodes 45a-45b shown in FIG. 3 may be operated in a mono-polar mode (with groundplate) but preferably are operated in a bi-polar mode to provide controlled energy delivery to achieve a particular temperatures between the adjacent paired electrodes 45a-45b in the wall W of the LES proximate to the electrodes. The electrodes are of any suitable biocompatible conductive material which conduct current to and from tissue around the LES in direct contact with electrodes 45a-45b.

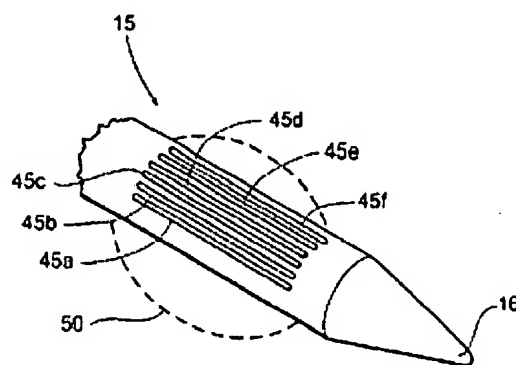
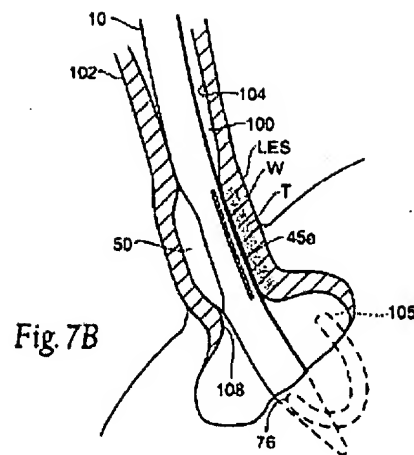


Fig. 4

shown in FIG. 4. In FIG. 4, the alternative embodiment is shown with six longitudinal electrodes 45a-45b. The embodiment of FIG. 4 thus may be operated in a mono-polar mode or in a bi-polar mode with a computer controller 60 (see FIG. 1) operatively connected to the Rf source 40 and electrodes and temperature sensors to multiplex (of vector) the current flow between and among various paired electrodes. (It should be appreciated that working end 15 may carry only a single electrode operated in a mono-polar mode and fall within the scope of the invention).

In the preferred embodiment described above, the elongate configuration of the electrodes and their longitudinal orientation was selected because it is believed that Rf energy delivery to elongate regions of the LES will prove optimal to accomplish the objectives of methods of the invention. As

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Referring to FIG. 7B, the diameter of extension member 10 may fit somewhat loosely or snugly in esophageal lumen 100 depending on the diameter of device selected. As shown in FIG. 7C, the physician preferably (but optionally) inflates balloon 50 with an inflation medium, for example air or saline solution from a syringe (not shown). Balloon 50 is inflated to a sufficient dimension to press the surface of working end 15, and more particularly electrodes 45a and 45b, into firm contact with surface 104 of targeted tissue in wall W of the LES. (It should be appreciated that a flexible fiberscope 105 (phantom view) may be introduced through a optional working channel 76 to view the gastro-esophageal junction 108 from inside the patient's stomach 110 which may be useful in positioning the device (see FIG. 7B)). The physician selects the treatment site based on anatomical knowledge of the LES and is thus capable of avoiding thermal energy delivery to certain areas or sides of the LES if so desired.

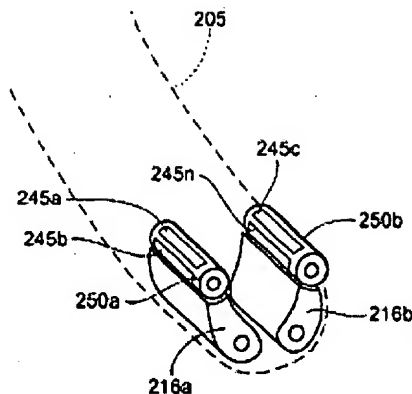


Fig. 11A

FIG. 11A illustrates another embodiment of Type "B" device in which roller elements 250a and 250b are carried in arm elements 216a and 216b to progressively engage the wall W of the LES and deliver RF energy between various paired electrodes 245a-245n in the roller elements 250a and 250b. This manner of RF energy delivery was disclosed in

Based on the above evidence, the method disclosed by Shadduck shows and teaches or suggest a "cylindrical vibrational transducer to be positioned with an inflated balloon in the body lumen".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-9, 12-15, 20-23, 37; 38, 40-47, 50, 51, and 54-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Shadduck (US 6740082). Shadduck discloses an instrument and method for treatment of the lower esophageal sphincter. Although much of the disclosure is directed to Rf sources, Shadduck states that other sources of energy such as ultrasound or high-energy focused ultrasound known in the art may be used in place of the Rf source (col 8, lines 10-15). Energy is delivered to a targeted tissue volume to accomplish controlled remodeling of the tissue (col 2, lines 50-52), where the target tissue is an anatomic lumen, such as the esophagus or the urethra (col 2, line 60). The energy electively injures cells to induce a biological response, which causes collagen formation (col 3, line 5) and additionally causes ionic agitation (col 3, line 45), and shrinking of tissue (col 3, line 32) including contracting longitudinally (col 4, line 38), which reduces compliance of the tissue. The injury of cells inherently interrupts their

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normal functions, such as interrupting nerve pathways and the ability to absorb food. Intestinal metaplasia is just one type of tissue found in the esophagus, which may be selectively remodeled by the system and is merely an intended use of the system, which is inherently capable of destroying, specific tissues in the esophagus. Alternative uses disclosed include endoscopically accessing a hiatal hernia in the abdominal cavity (col 17, lines 5-6) where the lumen would be the diaphragmatic sphincter. Energy is used to heat temperature in the range of 40 to 70 degrees Celsius, which is within the range of 55 to 95 degrees (col 3, line 27). A sensor array is used to measure temperature levels of a portion of the wall in contact with the sensor (col 10, line 16-18), wherein the wall consists of more than just the luminal surface. Additionally, temperature measurements of surface temperatures along the lumen surface (col 10, line 50), which can also be used to ensure over a certain maximum temperature is not reached during treatment (col 11, line 18). A cooling means may be circulated to maintain surface of the esophageal lumen (col 17, line 59). An elongate member, or catheter, with a working end is used to introduce the system to the lumen or target tissue (col 7, line 53-55). A balloon made of an elastomeric material is used which is inflatable until it contacts the surface of the target tissue in the wall of the LES (col 12, line 35-38). Alternatively, tissue maybe captured between movable opposed elements (figure 12A, elements 252a and 252b) with transducers (figure 12A, elements 245a and 245b) that direct energy to the captured tissue. The instrument includes a working channel that allows an endoscope or another instrument to be introduced (col 6, lines 44-45).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Hutchinson, et al (US 6929608). Shadduck, as discussed above, substantially discloses the invention, as claimed, however fails to explicitly disclose the energy range used. Hutchinson teaches that it is well known in the art to use a range from 0 to 30 W/cm² (figure 11) for the deposition in body tissue for thermal therapy (col 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Hutchinson in order to use a well-known energy range for proper tissue treatment.

Claims 11, 24, 25, and 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Ingle, et al (US 6976492). Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to explicitly disclose the duty cycle used and the use of a phased array. Ingle teaches the use of a 50% duty cycle (col 7, lines 26-29), which falls in the range of 10% to 100%, for the improved shrinking of tissues. Additionally, a phased array ultrasound transmitter is used (col 8, lines 50-51). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in

the reference by Ingle to include a 50% duty cycle for improved treatment of target tissues and a phased array for enhanced targeting flexibility (col 8, line 50).

Claims 17, 48, and 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Houser (US 5865801). Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to disclose the use of axially spaced apart balloons. Houser discloses a system including balloons surrounding an ultrasonic transducer. The pair of balloons are axially spaced apart (figure 3) and thereby center the transducer. The balloon compartments are each filled with fluid and Houser further states that the balloon may be constructed to have any desired number of compartments. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Houser to include multiple axially spaced balloons to advantageously provide better support and positioning capabilities.

Claims 16, 18, 19, 26, 27, 28, 30-34, 36, 52, 57, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Chapelon, et al (US 5720287). Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to disclose details of the relationship between the balloon and the transducer itself. In regards to claims 19 and 27, Shadduck, as previously discussed, discloses cooling of the fluid medium in the balloon to cool the luminal surface as well as viewing the target tissue through an endoscope. In regards to claims

30-32, Shaddock additionally discloses a balloon that is expanded against the body lumen for treatment, including the area adjacent to the opening as well as the entire opening (figures 7a and 7b). Chapelon discloses a therapy probe for ultrasound therapy and further teaches a transducer probe surrounded by a flexible membrane (figure 9, element 120), which is filled with an acoustic-coupling liquid such as water or an oil (col 4, lines 41-44). The transducer is movable with respect to the flexible outer casing of the probe (col 2, line 15-16), which may be focused through pivotal mounting. The probe may be rotated, pivoted, or translated (col 8, lines 14-16) and multiple transducers may be used, exemplarily using one for imaging and one for treatment, as seen in figure 9. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shaddock in light of the teachings in the reference by Chapelon to include increased mobility of the probe and transducer to advantageously increase the number of target areas able to be reached by the ultrasonic treatment.

Claim 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Shaddock in view of Chapelon as applied to claim 26 above, and further in view of Makower, et al (US 6302875). Shaddock in view of Chapelon, as discussed above, substantially discloses the invention as claimed, however fails to disclose the used of a circumferential array transducer. Makower discloses a system for an ultrasound catheter that may be inserted into blood vessels or other body lumens and further teaches the use of a circumferential array (claim 22). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of

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Shadduck in view of Chapelon in light of the teachings in the reference by Makower to include a circumferential array, as a luminal anatomical structure (col 1, line 28) is circumferential and therefore the use of this array will advantageously increase the number of target areas.

Claim 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Chapelon as applied to claim 26 above, and further in view of Jang (US 4744366). Shadduck in view of Chapelon, as discussed above, substantially discloses the invention, as claimed, however fails to disclose the used of multiple coaxial balloons. Jang discloses a catheter, which analogously uses balloons to obtain proper placement of the catheter and to provide contact with a lumen wall. Additionally Jang teaches the use of multiple balloons that are independently inflated, and thereby translated, to provide desired positioning (figure 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in view of Chapelon to include multiple coaxial balloons to provide improved control in positioning the catheter and a greater range of available balloon diameters.

Claims 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Sliwa, Jr., et al (US 2005/0245918). Shadduck, as discussed above, substantially discloses the invention as claimed, including capturing luminal tissue between opposed elements. However, Shadduck fails to disclose the use of a vacuum to draw tissue between said elements. Sliwa discloses a system for ablation of

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tissue in which the device, as in Shadduck, also comes into contact with the targeted tissue. Sliwa additionally teaches that a vacuum source (col 26, line 22) is used to hold the target tissue against the ablation device. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Sliwa to include a vacuum, as holding the target tissue improves the accuracy in treating only the desired tissue.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Makower. Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to disclose the use of a circumferential array transducer. Makower discloses a system for an ultrasound catheter that may be inserted into blood vessels or other body lumens and further teaches the use of a circumferential array (claim 22). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Makower to include a circumferential array, as a luminal anatomical structure (col 1, line 28) is circumferential and therefore the use of this array will advantageously increase the number of target areas.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John F. Ramirez whose telephone number is (571) 272-8685. The examiner can normally be reached on (Mon-Fri) 7:30 - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JFR


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